

§ 425.300

(b) To be eligible to participate in the Shared Savings Program after a previous termination, the ACO must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

(c) An ACO under the one-sided model whose agreement was previously terminated may reenter the program only under the two-sided model unless it was terminated less than half way through its agreement under the one-sided model in which case it will be allowed to re-enter the one-sided model. An ACO under the two-sided model whose agreement was terminated may only re-apply for participation in the two-sided model.

Subpart D—Program Requirements and Beneficiary Protections

§ 425.300 Compliance plan.

(a) The ACO must have a compliance plan that includes at least the following elements:

(1) A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

(2) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(3) A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

(4) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(5) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

(b)(1) ACOs that are existing entities may use the current compliance officer if the compliance officer meets the requirements set forth in paragraph (a)(1) of this section.

(2) An ACO's compliance plan must be in compliance with and be updated

42 CFR Ch. IV (10–1–14 Edition)

periodically to reflect changes in law and regulations.

§ 425.302 Program requirements for data submission and certifications.

(a) *Requirements for data submission and certification.* (1) The ACO, its ACO participants, its ACO providers/suppliers or individuals or other entities performing functions or services related to ACO activities must submit all data and information, including data on measures designated by CMS under § 425.500, in a form and manner specified by CMS.

(2) *Certification of data upon submission.* With respect to data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, an individual with the authority to legally bind the individual or entity submitting such data or information must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge information and belief.

(3) *Annual certification.* At the end of each performance year, an individual with the legal authority to bind the ACO must certify to the best of his or her knowledge, information, and belief—

(i) That the ACO, its ACO participants, its ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are in compliance with program requirements; and

(ii) The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS.

(b) [Reserved]